## REMARKS

Applicants' attorney thanks the Examiner for the Office Action, which indicates that Claims 12-43 have been withdrawn from consideration. The Office Action also contains rejections of all of the elected pending claims (i.e., Claims 1-11). More particularly, the Office Action contains both prior art-based rejections and non-prior art-based (i.e., formal) rejections of Claims 1-11. By the foregoing amendments, Claims 1-11 have been cancelled, and new Claims 44-68 have been added.

Applicants' attorney notes that the present application, as filed, did not include a claim numbered 31. In other words, Claim 31 was inadvertently numbered Claim 32, resulting in Claims 31-43 being numbered Claims 32-44. This typographical error was noted by the Examiner in the Office Action mailed on October 9, 2007. Applicants' attorney has corrected this numbering error by renumbering Claims 32-44 as Claims 31-43.

### Claim Rejections - 35 USC § 112

Claims 1-11 were rejected under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded to be the invention. The terms used in Claims 1-11 and the construction of those claims were both characterized as confusing and unclear in the Office Action.

As noted above, Claims 1-11 have been cancelled by the foregoing amendment. In such circumstances, applicants' attorney respectfully submits that the

35 USC § 112, second paragraph rejections of Claims 1-11 have been obviated and are now rendered moot.

**Claim Rejections - 35 USC § 103**

Claims 1-11 were also rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,782,835 to Hart et al. ("the Hart et al. Patent") taken with an article by Bugbee ("the Bugbee article") in view of an article by Peretti et al. ("the Peretti et al. article"). More particularly, the Examiner has taken the position that it would have been obvious to one skilled in the clinical art (at the time the invention was made) to modify the cartilage repair implant of the Hart et al. Patent, taken with the use of **fresh** osteochondral allografts **containing chondrocytes** taught by the Bugbee article, such that the implant is surrounded by a mixture of milled allograft cartilage pieces or mixture in a biocompatible carrier, as disclosed in the Peretti et al. article.

With further reference to the Hart et al. Patent, it describes an articular cartilage repair implant and an associated procedure which includes cutting a bone plug **from a bone of a patient undergoing the procedure** (i.e., an **autograft** plug), and removing the bone plug using a plug removal tool 30 (see col. 9, lines 26-40). A surgeon performing this procedure then **immediately** places the autograft bone plug into the hole at the site of articular cartilage damage using an emplacement tool 80 (see col. 3, lines 24-27 and col. 9, lines 40-53). The hole drilled in the donor (i.e., patient) during the harvesting of the bone plug is then filled with one or more collagen plugs.

In contrast to the **autograft** bone plug disclosed in the Hart et al. Patent, new independent Claim 44 recites a cartilage repair implant which includes an **allograft** plug (i.e., a graft of bone tissue from another individual of the same species as the recipient). One improvement recited in new Claim 44 is that the **allograft** plug is **decellularized** such that the bone base and cartilage cap thereof are **substantially free of cellular material**. On the other hand, the autograft bone plug disclosed in the Hart et al. Patent necessitates **immediate** implantation, which would indicate that such allografts have **not** been decellularized or otherwise processed. The Hart et al. Patent neither discloses nor suggests that the autograft undergoes **decellularization** or any processing to remove the cellular material therein.

Turning to the Bugbee article, while it does disclose the use of allografts to repair articular cartilage defects, the allografts are **fresh** osteochondral allografts that contain **viable chondrocytes** (see page 158). The Bugbee allograft thus differs from the **decellularized** allograft bone plug recited in Claim 44. More particularly, the freshness of the allografts disclosed in the Bugbee article and the fact that such allografts contain **viable chondrocytes** would indicate that such allografts have **not** been **decellularized**, or otherwise processed. The Bugbee allografts are procured within 24 hours of the donor's death, and typically implanted within 72 hours, although transplantation may be performed up to seven days from harvesting if the allograft is properly stored (see page 159). In other words, due to their freshness and the inclusion of live chondrocytes, the Bugbee allografts must be implanted **as soon as possible** into a cartilage defect. Thus, the Bugbee article neither discloses nor

suggests that the allograft undergoes **decellularization** or any processing to remove the cellular material therein.

Not only is there no disclosure or suggestion of the decellularized allograft bone plug recited in Claim 44 in either the Hart et al. Patent or the Bugbee article, both of these documents **teach away** from the decellularization of the bone plug. More particularly, decellularizing, or otherwise processing the Hart et al. bone plug would delay the implantation thereof, and would have to be performed **separately** from the surgical procedure disclosed in the Hart et al. Patent, thereby complicating and delaying that surgical procedure and being contrary to the intended purpose of the Hart et al. bone plug. Similarly, decellularizing the Bugbee allograft would compromise its freshness by destroying the viable chondrocytes therein, and would also delay the implantation of the allograft and would be contrary to the intended purpose of the Bugbee allograft.

Another improvement recited in new Claim 44 is that an **allograft** milled cartilage mixture, which includes a biocompatible carrier, at least partially fills the space between the bore and a second sidewall portion of the decellularized plug to thereby enhance tissue integration between the decellularized plug and adjacent host tissue. The Office Action indicates that the Examiner's postulated Hart et al./Bugbee combination does **not** disclose a cartilage repair assembly including an allograft milled cartilage mixture in a biocompatible carrier surrounding at least a portion of a sidewall of the allograft bone plug (as recited in original, now cancelled, Claim 1). The Office Action then asserts that one of ordinary skill in the clinical art would be motivated to

modify the Examiner's postulated Hart et al./Bugbee combination implant to include the cartilage mixture disclosed in the Peretti et al. article.

With reference to the Peretti et al. article, it discloses a study in which cartilage chips were combined with **chondrocytes** suspended in fibrinogen, and the resulting mixture was implanted into experimental animals (Materials and Methods, page 568). However, neither the Peretti et al. article nor any of the other references made of record discloses or suggests the **combination** of an allograft milled cartilage mixture and a **decellularized** allograft plug, as recited in new Claim 44. Therefore, Applicants' attorney respectfully submits that the Hart et al. Patent, the Bugbee article and the Peretti et al. article, whether considered alone or in combination with each other, fail to suggest the cartilage repair implant recited in new Claim 44.

**Provisional Double Patenting Rejections**

The Office Action also contains two provisional nonstatutory obviousness-type double patenting rejections, which are addressed individually below:

1. Claims 1-11 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the apparatus claims (i.e., Claims 1-7 and 16) of Application Serial No. 10/960,960 ("the '960 Application"). As noted above, Claims 1-11 of the present application have been cancelled by the foregoing amendments. Applicants' attorney therefore respectfully submits that this provisional double patenting rejection is rendered moot.

Applicants' attorney also respectfully submits that this provisional double patenting rejection is rendered moot in connection with new Claims 44-68 for the

following reason. As preliminarily amended, the '960 Application contained both product claims (i.e., Claims 1-7 and 16), and method claims (i.e., Claims 8-15, 17 and 19-30). In an Office Action mailed October 23, 2006, the Examiner to which the '960 Application was assigned indicated that the product claims and the method claims constituted distinct inventions, and required a restriction to one invention. In response to the restriction requirement, the product claims (i.e., Claims 1-7 and 16) were elected and the method claims were withdrawn from consideration in an election made on November 20, 2006.

Subsequently, the '960 Application was allowed to go abandoned after a related divisional application was filed on March 26, 2008. The new divisional application (i.e., U.S. Patent Application Serial No. 12/079,629) contains only the originally-filed method claims that were withdrawn from the '960 Application (i.e., Claims 8-30). In the foregoing circumstances, applicants' attorney respectfully submits that a double-patenting rejection of new product Claims 44-68 may not be properly based on either the abandoned '960 Application or the aforementioned divisional application with method claims directed to a separate and distinct invention.

2. Claims 1-11 were also provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-42 of co-pending Application Serial No. 10/438,883 ("the '883 Application"). Independent Claim 1 of the '883 Application recites an allograft bone plug that is "sized to have an interference fit in a drilled bore in a cartilage defect area." Independent

Claim 23 of the '883 Application similarly recites an allograft bone plug that is "sized to have an interference fit in a drilled bore in a cartilage defect area." Independent Claim 24 of the '883 Application recites a "shaped structure being dimensioned to have an interference fit in a cut out area of cartilage defect..." Independent Claim 34 of the '883 Application also recites a shaped structure that has "been dimensioned to fit in a cut out formed in a cartilage defect area so that said shaped structure is in an interference fit in said cut out." Independent Claim 38 and independent Claim 42 of the '883 Application recite a "shaped structure being dimensioned to fit in a bore cut in a cartilage defect area so that said shaped structure is in an interference fit in said bore." Independent Claims 43 and 49 of the '883 Application also recite the interference fit between an allograft plug and a hole cut in a patient at a cartilage defect area site. Thus, all of the pending independent claims of the '883 Application recite the aforementioned "interference fit" feature. Furthermore, all of the dependent claims of the '883 Application include the "interference fit" feature, as each dependent claim depends from one of the independent claims of the '883 Application.

Applicants' attorney also notes that dependent Claims 6, 7 and 29 of the '883 Application recite a plurality of grooves on the outer surface of the bone plug (the sterile shaped structure in Claim 29), while Claim 38 recites a plurality of channels formed on the outside surface of the sterile allograft shaped structure. Notwithstanding such grooves and channels, the devices recited in these claims are dimensioned to have an interference fit with the drilled bore, as recited in the associated base independent claims.

In contrast, independent Claim 44 of the present application recites an allograft bone plug including a sidewall that is sized and shaped such that a first portion of the sidewall engages a bore drilled in a cartilage defect area of host tissue, and such that a second portion of the sidewall does **not** engage the bore, thereby forming a space between the bore and the second sidewall portion.. Claim 44 further recites an allograft milled cartilage mixture, which includes a biocompatible carrier, that at least partially fills the space between the bore and the second sidewall portion of the plug to thereby enhance tissue integration between the plug and adjacent host tissue. This structure and arrangement would **impede or prevent** an interference fit between the bore and the sidewall of the allograft bone plug.

None of the pending claims of the '883 Application recite a sidewall having first and second portions, the second portion not engaging the bore, and the resulting formation of a space between the bore and the second sidewall portion. Further, none of the claims of the '883 Application recite the placement of allograft milled cartilage mixture into a space between the bore and the sidewall of the plug. These features, if recited in the claims of the '883 Application, would impede or prevent the interference fit feature recited therein. In the foregoing circumstances, applicants' attorney respectfully submits that a double-patenting rejection of new independent Claim 44 may not be properly based on the '883 Application.

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In view of the foregoing amendments and remarks, applicants' attorney respectfully submits that new Claim 44 is directed to patentable subject matter and, in the absence of any other rejections, such claim should be in condition for allowance. Because Claims 45-68 depend from Claim 44, they are believed to be in condition for allowance for the same reasons that Claim 44 is allowable. Accordingly, applicants' attorney respectfully requests the consideration and allowance of Claims 44-68. If such action cannot be taken, the Examiner is cordially invited to place a telephone call to applicants' attorney in order that any outstanding issue may be resolved.

The accompanying Petition for a three-month extension of time authorizes the Examiner to charge the associated $1,050 extension fee to Deposit Account No. 501561. The Examiner is also hereby authorized to charge an extra claim fee of $910 for the fourteen (14) additional claims in excess of twenty (20) and the one (1) independent claim in excess of three (3). If there are any additional fees due as a result of this Response, including extension and petition fees, the Examiner is hereby authorized to charge them to Deposit Account No. 501561.

Respectfully Submitted,

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